Update on the Respiratory Diseases Research Program

For the NIOSH Board of Scientific Counselors
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Appendices

Abbreviations Used in Report

ACBS: Asthma Call-Back Survey
AHS: Agricultural Health Study
BLS: Bureau of Labor Statistics
BRFSS: Behavioral Risk Factor Surveillance System
Cal/OSHA: California Division of Occupational Safety and Health
CDC: Centers for Disease Control and Prevention
CDPH: California Department of Public Health
COPD: chronic obstructive pulmonary disease
CWP: coal workers' pneumoconiosis
EHR: electronic health record
FEV1: forced expiratory volume in 1 second
HHE: health hazard evaluation
HMW: high molecular weight
HRCT: high resolution computed tomography of the chest
I/O: industry and occupation
ILO: International Labour Office
IOM: Institute of Medicine
JEM: job-exposure matrix
LMW: low molecular weight
MESA: Multi-Ethnic Study of Atherosclerosis
NA: National Academies
NCEH: National Center for Environmental Health
NCHS: National Center for Health Statistics
NHANES: National Health and Nutrition Examination Survey
NHIS: National Health Interview Survey
NIOSH: National Institute for Occupational Safety and Health
NORMS: National Occupational Respiratory Mortality System
OA: occupational asthma
ONC: Office of the National Coordinator for Health Information Technology
OPA: ortho-phthaldehyde
OSHA: Occupational Safety and Health Administration
PHDSC: Public Health Data Standards Consortium
RDRP: respiratory diseases research program
REL: recommended exposure limit
VOC: volatile organic compound
WEA: work-exacerbated asthma
WoRLD Report: Work-Related Lung Disease Report
WRA: work-related asthma
WTC: World Trade Center

Introduction

To be in compliance with the Government Performance and Results Act, the National Institute for Occupational Safety and Health (NIOSH) must identify performance targets and track progress towards those targets over time: http://www.cdc.gov/fmo/topic/Performance/performance_docs/FY2012_CDC_Online_Performance_Appendix.pdf. One of NIOSH's current performance targets is to track the progress of several NIOSH programs that underwent National Academies (NA) reviews several years ago in implementing the recommendations of those reviews. The Respiratory Diseases Research Program (RDRP) is one such program. RDRP includes all individuals and groups supported by NIOSH to do work that is relevant to occupational respiratory diseases, whether intramural or extramural. RDRP is defined in that manner because this inclusive view is the one most relevant to NIOSH's societal impact in the area. This report to the NIOSH Board of Scientific Counselors documents RDRP progress from 2008 to the present in addressing the 5 highest-priority NA recommendations to the program.

Selection of priorities and implementation of plans to address them has been an ongoing process since the NA report *Respiratory Diseases Research at NIOSH* was released in 2008: http://www.nap.edu/catalog.php?record_id=12171. That review was very positive. RDRP received a score of 5/5 for relevance and 4/5 for impact. The evaluation committee indicated that had it been able to give a fractional rather than integer score, the score for impact would have been between a 4 and a 5. The committee also made many recommendations for maintaining and improving RDRP.

In 2009, RDRP developed an implementation plan in response to the NA review that reflected input from across NIOSH. It listed all the NA recommendations and it identified the highest priorities from among them. These were digital chest imaging, flavorings-related lung disease and occupational respiratory disease surveillance: http://www.cdc.gov/niosh/nas/pdfs/RDRP_Implement_for_BSC2.pdf. The Board of Scientific Counselors reviewed the implementation plan in 2009 and approved it.

In 2011, RDRP was asked to identify highest priority recommendations from the NA review to be tracked for purposes of compliance with the Government Performance and Results Act. RDRP selected the 3 existing high priorities, plus 2 more high priority recommendations to address work-related asthma (WRA) and work-related chronic obstructive pulmonary disease (COPD). These 5 priority areas were endorsed by the NIOSH Board of Scientific Counselors in 2011.

In addition to the planning and priority-setting activities noted above, RDRP has engaged in ongoing internal planning and review of its priorities since 2008. A cross-Institute RDRP steering committee reviews the program's strategic goals in detail annually and makes adjustments as appropriate. This group also plays an important role in making intramural funding decisions responsive to the strategic goals. Current RDRP Strategic Goals are included as Appendix 1. RDRP goals cited in this report have been drawn directly from that list.

Each of the five priorities to be reviewed is described in a separate section. Each section is supported by an appendix containing supporting materials including references. These are Occupational Respiratory Disease Surveillance – Appendix 2; Digital Chest Imaging – Appendix 3; Flavorings-Related Lung Disease – Appendix 4; COPD – Appendix 5; and Work-Related Asthma – Appendix 6.

Occupational Respiratory Disease Surveillance

Text from NA Report: "Systems for Surveillance: NIOSH should provide appropriate resources for and engage in high-priority occupational [respiratory] disease surveillance." (p136)

Responsive RDRP Goal: Improve surveillance and workforce screening for work-related respiratory diseases.

Status: In progress

Background: Surveillance is critical for RDRP planning, priority setting, and tracking of progress. Unfortunately, major sources of occupational surveillance data such as the Bureau of Labor Statistics' (BLS) *Survey of Occupational Injuries and Illnesses* do a far better job of identifying occupational injuries than occupational diseases, including respiratory diseases. One major problem is undercounting of occupational diseases such as work-related asthma (WRA). These diseases are often attributed to non-occupational causes and the occupational contribution is not recognized or recorded. Another important problem is diseases of long latency, such as pneumoconiosis or chronic obstructive pulmonary disease. Because these may not have onset for years, often after the worker has moved to a new job or even retired, they are not captured in BLS data. Occupational diseases of long latency are also often attributed to non-occupational causes, compounding the difficulty in recognizing and accurately tracking them. Thus, maintaining and updating existing morbidity, mortality and hazard surveillance relevant to occupational respiratory disease and developing innovative approaches for improvement are extremely important to RDRP.

External Factors: Challenges in identifying occupational respiratory disease, as noted above. There is a need for collaborations to access a patchwork of data sources not primarily designed for tracking occupational respiratory disease, such as mortality data and large national surveys.

Implementation of Recommendation

Activity A: Conduct surveillance for work-related respiratory diseases using available data sources, including mortality data, cancer center data, other national data sources or studies, and/or State-based surveillance, with ongoing analysis and dissemination of results.

Description/Relevance/Sustainability: RDRP maintains a number of surveillance products, many of which can be accessed via the occupational respiratory diseases web home page at: http://www.cdc.gov/niosh/topics/surveillance/ords/ . These are updated regularly, and provide health and hazard surveillance data from a range of sources. Maintaining, updating, and improving these resources is directly responsive to the NA recommendation and the RDRP goal. This activity is sustainable, due to dedicated allocation of personnel and resources to the effort.

Progress: There has been important progress in this area. RDRP has leveraged national surveillance systems by applying them, as possible, to occupational respiratory disease surveillance and by enhancing them through the addition of relevant questions. For example, questions related to work and work-relatedness of asthma and COPD have leveraged investments in national surveys such as the National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), and the Behavioral Risk Factor Surveillance System (BRFSS) to gain new insights into the burden and impact of occupational respiratory disease. RDRP has also partnered with states to conduct state-based surveillance, focused in particular on work-related asthma and silicosis.

Impact: The NIOSH Work-Related Lung Disease (WoRLD) Report is a major source for up to date national morbidity, mortality, and hazard surveillance information relevant to occupational respiratory disease: http://www2.cdc.gov/drds/worldreportdata/. Since 2008, it has been converted to electronic format, allowing for ongoing updating of its content. A full update was completed in March, 2012. It had 6879 visits over the 9-month period from 7/11 to 3/12. Another important source of national data about occupational respiratory disease is the National Occupational Respiratory Mortality System (NORMS), which enables users to easily obtain national mortality data customized to their information needs: http://webappa.cdc.gov/ords/norms.html. NORMS had 6472 visits from 7/11 to 3/12. This innovative system is updated annually. Another source of national-level information has been through RDRP participation in large national surveys such as NHANES, NHIS, and BRFSS. Examples of these activities will be discussed in the sections on chronic obstructive pulmonary disease (COPD) and work-related asthma.

State-based surveillance has been another active area of effort: http://www.cdc.gov/niosh/topics/surveillance/ords/StateBasedSurveillance.html. NIOSH currently funds 23 states to conduct population-based surveillance: http://www.cdc.gov/niosh/oep/reports.html#surv. In addition, some states are funded to carry out case-based or "expanded" sentinel surveillance. In the area of occupational respiratory diseases, efforts are focused on silicosis (2 states) and/or WRA (5 states). RDRP has provided technical support and subject-matter expertise to assist states in these surveillance activities, as well as in dissemination of information and intervention activities. From 2008 to 2011, RDRP conducted 4 meetings with states conducting WRA surveillance and 3 meetings with states conducting silicosis surveillance. Typically, 4 to 7 representatives from non-funded states also participated in these meetings. Interactions have motivated the Council of State and Territorial Epidemiologists to develop a Position Statement calling for silicosis to be a nationally notifiable condition and to advocate for considering asthma hazards when using cleaners and disinfectants. States have produced numerous pieces of outreach material, many of them accessible through the NIOSH state-based occupational health surveillance clearinghouse: http://wwwn.cdc.gov/niosh-survapps/statedocs/. State-based surveillance has also resulted in a number of research publications (Appendix 2). These have brought attention to issues such as the importance of cleaners and disinfectants and indoor air quality in WRA.

Future plans: RDRP will continue to work to improve the data available for planning, priority setting, and tracking progress in the prevention of occupational respiratory diseases and communicating this information to those who would benefit from it. An important strategy will be to continue to leverage existing data and systems for occupational respiratory disease surveillance by working with other Federal agencies, parts of CDC, state and local government, etc. We will use these sources of data to maintain and update surveillance products such as eWoRLD and NORMS and to publish peer-reviewed research. We will also continue to be opportunistic, seeking innovative approaches to surveillance, such as by using electronic health records (described below).

Activity B: Develop, demonstrate, and disseminate innovative approaches to surveillance for work-related respiratory diseases, including use of information from the healthcare system such as information in electronic health records (EHRs).

Description/Relevance/Sustainability: Health care in the United States is undergoing a significant change as providers of health care transition from paper-based records to EHRs. Unfortunately, EHRs do not generally collect patient work information such as industry and occupation (I/O) in a systematic, standardized way that facilitates conversion (coding) into structured electronic data that can be used for automated clinical decision support or for public health surveillance. Because of the potential for EHRs to improve clinical care for those with occupational respiratory diseases and their potential to improve surveillance (particularly morbidity surveillance) for these conditions, RDRP has as strong interest and has been directly involved in developing these capabilities. Although the text here focuses on EHRs, RDRP also

has a strong interest in other innovative approaches to surveillance such as mining data from workers' compensation systems and using web-based surveys to collect surveillance information. The efforts described here are directly responsive to NA recommendations and to RDRP goals. They are sustainable, because personnel and resources have been directed to address them.

Progress: Over the past several years, there has been great progress in addressing the goal of harnessing EHRs to track work-related conditions and improve care for these conditions. There has been commitment of personnel, with a cross-Institute working group developed to move the work forward. A full time coordinator for the group has been hired and a contract to bring on an EHR informatics specialist has been implemented. NIOSH commissioned the Institute of Medicine (IOM) to examine the area and make recommendations; their report was published in September, 2011. NIOSH participates in the CDC Meaningful Use Advisory Group and in strategic planning at CDC to ensure public health utility of electronic health records. NIOSH has become very active in the Public Health Data Standards Consortium (PHDSC), which is a national non-profit membership-based organization of federal, state, and local health agencies; professional associations, academia; and public and private sector organizations that represents the public health community in national efforts to standardize health information for healthcare and population health. An RDRP investigator currently serves as the Vice President and is the federal liaison to the PHDSC. NIOSH has actively engaged with the Office of the National Coordinator for Health Information Technology (ONC), which has authority for implementation of EHRs in the U.S., as well as with other partners.

Impact: IOM released its report late in 2011: http://www.cdc.gov/niosh/updates/upd-10-03-11.html. IOM supported the NIOSH effort, and the report contained a number of helpful recommendations. The proposal "Evaluating the feasibility of real time autocoding of industry and occupation in electronic health records systems," which addresses IOM recommendations for standardized approaches to I/O coding, was a winner of the CDC 2012 Innovation Fund Challenge. NIOSH submitted comments in support of the Center for Medicare and Medicaid Services' and ONC's proposed rules for Meaningful Use Stage 2 which would make cancer reporting one of the means by which Eligible Providers could demonstrate meaningful use. NIOSH is working closely with the Cancer Surveillance Branch of CDC's Division of Cancer Prevention and Control to support capture of "usual" occupation and industry in these reports, which is required in most states. NIOSH was invited to testify to the Meaningful Use Workgroup of the Health Information Technology Policy Committee (a federal advisory committee to the ONC) about the utility and feasibility of including I/O information as part of Stage 3. NIOSH recommended incorporation of occupational information as core demographic data to support efforts to address health disparities. Preliminary recommendations presented by the workgroup on August 1, 2012, support the inclusion of I/O codes as part of demographic data and the inclusion of disability status as part of Stage3 meaningful use rules. Interactions with NIOSH have played a role in several organizations taking action in this area. The Council of State and Territorial Epidemiologists developed a position statement "Inclusion of Occupation and Industry as core data elements in Electronic Health Record systems and in recommended elements in other minimum data sets" which calls for NIOSH to implement the recommendations outlined in the IOM report. The American College of Occupational and Environmental Medicine has reached out to engage with NIOSH, supporting the effort and seeking to work together to address ethical and privacy protections for electronic records and to develop mechanisms to enable clinical decision support through structured occupational data. The Association of Occupational and Environmental Clinics (AOEC) has organized discussions at regional meetings of member clinics to learn about the current status of EHRs in occupational health practice and will provide NIOSH with reports from all four regions by the end of 2012.

Future Plans: NIOSH will pursue a number of activities to include and achieve "meaningful use" of I/O data in EHRs, providing clinical and public health benefits. We will continue efforts to develop a system for

automated coding of I/O information for inclusion in EHRs. We will work with PHDSC on a project to develop implementation standards that ensure consistent use and exchange of occupation information. We will also engage a clinically based health information technology group to develop approaches for individuals to self-enter their occupational history into EHRs. We put forward a Request for Information to learn more about current work in clinical settings using I/O information and will be assessing those responses in the fall. Pending project proposals include a demonstration project assessing feasibility of incorporating work information into EHRs and improving case-based surveillance; and a project to develop and pilot clinical decision support tools to assist in the diagnosis and management of potentially work-related conditions, such as new-onset asthma in adults. We are also planning to conduct a workshop in 2013 on privacy and security issues raised by including work-related information in EHRs to help inform our approach to these very important issues going forward.

Digital Chest Imaging

Text from NA Report: "The committee recommends that the effectiveness of digital radiography in CWP surveillance should be an important continuing research priority, which will extend to all interstitial lung diseases." (p135)

Responsive RDRP Goal: Perform studies and develop updated recommendations for chest imaging of pneumoconiosis that allow implementation of digital imaging for classification of chest radiographs using the International Labour Office classification system. Transition NIOSH's mandated surveillance activities, including the B reader certification program, to use of digital chest imaging.

Status: In progress

Background: Dust-induced lung diseases such as coal worker' pneumoconiosis (CWP), silicosis, and asbestosis continue to be important problems. Radiographic chest imaging is a necessary component of surveillance for these conditions and for targeting prevention efforts. The International Labour Office (ILO) classification system is widely used for standardized characterization of the presence and severity of changes compatible with pneumoconiosis in these images. Its use is mandated by federal law in several surveillance and compensation settings. Until late 2011, the ILO system could only be applied to film-based chest radiographs and could not be applied to modern digital chest images. Due to the widespread adoption of digital radiography in US clinical settings, this restriction was making radiographic surveillance that used the ILO system unfeasible. Thus, RDRP has been addressing the critical need for the public health community to transition medical screening and surveillance for pneumoconiosis from using film-based chest radiography to using modern digital chest imaging.

External Factors: NIOSH is mandated by federal law to provide radiographic surveillance to underground coal miners. Existing federal regulations specify using film-based radiographs and evaluating them using the ILO classification system. Regulations also specify that NIOSH maintain a certification program documenting physician competency in use of the ILO classification system. Stakeholders, including labor, management, and other government agencies all support enabling use of modern digital chest images for purposes of surveillance and compensation programs.

Implementation of Recommendation

Activity A: Perform studies

Description/Relevance/Sustainability: To have a scientific foundation for transitioning ILO classification of radiographic chest images from film-based to digital chest imaging, it was necessary to document whether, and under what technical conditions, the two modalities could yield similar classification results. This information did not previously exist. This research activity is highly relevant to the recommendation and the RDRP goal. The activity is sustainable, due to intramural personnel and resources and well-developed extramural collaboration, including with ILO.

Progress: There has been great progress over the past several years. Collaborative research with extramural partners documented equivalence of ILO classifications made using film technology vs. digital imaging using "DR" technology and display of images on high quality medical grade monitors. Printing out images and classifying the hard copy images increased the prevalence of images classified as showing small opacities (Franzblau et al 2009). Intramural research documented equivalence of ILO classifications made using film technology vs. digital imaging using "CR" technology with display of images on monitors (Laney

et al 2010). Digital images are more likely to be classified as being of high quality than film images (Laney et al 2011).

Impact: Since 2008, RDRP has published 5 peer-reviewed research papers. (See Appendix 3) These have formed the scientific basis for recommendations by ILO and NIOSH (see below). They have also formed the scientific basis for regulatory changes needed to enable transition of NIOSH coal workers' surveillance activities to digital technology (see below).

Future Plans: As infrastructure for future research, educational, and service efforts, NIOSH has established an electronic chest image repository: http://www.cdc.gov/niosh/topics/chestradiography/repository.html. Anonymous digitally-acquired chest images, chest computed tomography scans, and questionnaire information will be placed into the repository. The digital chest images will represent a range of abnormalities and will be well characterized for presence and severity of abnormalities using the ILO classification system. The repository will be an important source of images for research to develop and validate an updated, fully modernized ILO classification system. We also anticipate pursuing educational research to document effectiveness of teaching materials and the performance of the NIOSH certification examination on ILO classification. A longer-term goal, to be pursued in the future, will be to use validated repository images in an effort to develop computer-assisted ILO classification.

Activity B: Develop updated recommendations

Description/Relevance/Sustainability: In order to disseminate appropriate use of digital chest imaging for pneumoconiosis surveillance using ILO classification, it is necessary to have authoritative recommendations in place to guide implementation by practitioners. This activity is a necessary and critical component of the NA recommendation and is responsive to the RDRP goal. It is also sustainable, since intramural resources are available to develop and update guidance.

Progress: There has been much progress. In 2008, NIOSH held a workshop attended by a diverse group of international experts to develop a foundation for the work to follow. An outgrowth of the workshop was that NIOSH assisted ILO in updating its international guidance to enable use of digital images in the ILO classification system. NIOSH has also posted its own guidance on appropriate use of digital chest imaging. To enable practitioners to implement NIOSH guidance, NIOSH has developed software for image display and made it freely available for download from the NIOSH website.

Impact: A NIOSH document is based on the 2008 workshop: http://www.cdc.gov/niosh/docs/2008-139/WorkshopSummary.html. Several ILO products were subsequently developed with NIOSH assistance, including a guidance document http://www.ilo.org/safework/info/publications/WCMS_168260/lang--en/index.htm and a set of digitized standard comparison films that could be displayed on medical monitors http://www.ilo.org/safework/info/publications/WCMS_168337/lang--en/index.htm. NIOSH developed a detailed guidelines document*: Application of Digital Radiography for the Detection and Classification of Pneumoconiosis* http://www.cdc.gov/niosh/docs/2011-198/. In order to enable implementation of its guidelines, NIOSH also developed and posted "Bviewer©" software for ILO classification of digital chest images: http://www.cdc.gov/niosh/topics/chestradiography/digital-images.html#download. It is likely that other government programs, such as the Department of Labor's Black Lung Compensation Program, will use NIOSH guidance in updating efforts.

Future Plans: The most-recently updated ILO classification system uses digitized versions of film radiographs as standard comparison films, which have a different appearance than modern, digitally-acquired and processed images. Thus, NIOSH is partnering with ILO to more fully modernize the

classification system by moving to modern digitally-acquired standard films. This effort will use the previously-described image repository.

Activity C: Transition NIOSH's mandated surveillance activities, including the B reader certification program, to use of digital chest imaging.

Description/Relevance/Sustainability: In order to transition NIOSH's mandated surveillance activities to use of digital chest imaging, it is necessary to update regulations, because current regulations (42 CFR 37) specify the use of film-based chest radiographs. After updating regulations to enable use of digital chest imaging, it will be necessary to implement the new technology in NIOSH service, physician education, and physician certification programs. These are critical to the NA recommendation and responsive to the relevant RDRP goals. They are sustainable, due to dedicated personnel and funding for the activity.

Progress: Based on the scientific foundation described above, in January, 2012, RDRP posted a Notice of Proposed Rulemaking in the Federal Register. The proposed rule translates recent NIOSH recommendations into proposed regulations for implementation. Public comments received in response to the rule were mostly favorable. The proposed rule was edited in response to public comment and the final rule submitted for federal government clearance. It will be published in the near future. In preparation for implementation of the final rule, NIOSH has acquired the necessary hardware and software to operate its Coal Workers' Health Surveillance Program digitally. Participating clinics will be able to securely submit encrypted digital chest images to the program via the internet. Physician evaluators ("B readers") will be able to securely log in to the program image management system to view images, perform ILO classification and submit results. Beta testing of the system has already started using images not part of the mandated surveillance program. Anticipating updates to training and certification examination activities, high quality digitized copies of current images used in those activities have been prepared and evaluation of software for administering certification examinations in a digital environment has started. We have also met with the American College of Radiology, a long-standing partner, to discuss educational priorities and potential partnership opportunities in physician education and certification.

Impact: A notice of proposed rulemaking was published in the Federal Register: https://www.federalregister.gov/articles/2012/01/09/2011-33164/specifications-for-medical-examinations-of-underground-coal-miners. Digitized B reader study syllabus training materials are posted on the web: http://www.cdc.gov/niosh/topics/chestradiography/breader-study-syllabus.html.

Future Plans: We will finalize updated federal regulations that enable use of digital radiography in the Coal Workers' Health Surveillance Program. We will work to enroll clinical providers that use digital chest imaging into the program. We will also fully implement infrastructure for receiving digital images, distributing them to B readers for review, receiving results, and disseminating results to miners. We will work with partners such as the American College of Radiology to update teaching and testing materials to digital format and to implement digitally-based physician teaching and certification testing activities.

Flavorings-Related Lung Disease

Text from NA Report: "In the flavoring industry, the RDRP response to the identification of diacetyl-induced bronchiolitis obliterans has led to surveillance efforts in multiple locations in an effort to detect and prevent disease. The evaluation committee agrees that continued surveillance, prevention of exposures, and mechanistic research to better understand this disease should continue to be a high priority for the RDRP." (p134)

Responsive RDRP Goal: Prevent and reduce flavorings-induced obstructive lung disease, including bronchiolitis obliterans.

Status: In progress

Background: NIOSH identified flavorings-related lung disease as an emerging occupational respiratory disease after being requested in 2000 by the Missouri Department of Health and Senior Services to evaluate a cluster of 8 workers at a rural microwave popcorn production plant who had developed the rare disease, bronchiolitis obliterans. NIOSH subsequently identified a chemical component of butter flavor vapors, diacetyl, as causative. Subsequent work suggests that related alpha-diketone chemicals, such as 2,3-pentanedione have similar toxicity; exposures can cause other types of respiratory disease, such as disease with a restrictive pattern of spirometry; and causative exposures and disease can be found in other settings, such as flavoring and food production plants. NIOSH has vigorously pursued a range of multidisciplinary efforts to address this issue and to develop prevention recommendations.

External Factors: This area has attracted much attention from the media and the general public. Civil liability has become an important industry consideration. The current difficult economic climate and worries about job security affect workers' willingness to request and participate in Health Hazard Evaluations (HHEs).

Implementation of Recommendation

Activity A: Conduct surveillance, epidemiological studies, and field studies to identify the full range of food production industries at risk for flavorings- induced lung disease.

Description/Relevance/Sustainability: Under federal regulations, NIOSH has authority to conduct HHEs of workplaces requested by labor or management and to provide technical assistance to federal, state, or local government. These activities are critical and have played an important role in identifying and evaluating exposures and respiratory disease related to flavorings. In addition, NIOSH has authority to carry out workplace research studies, often referred to as industry-wide studies (flavorings-related example: http://www.gpo.gov/fdsys/pkg/FR-2008-03-06/html/E8-4333.htm). This activity is directly relevant to addressing the NA recommendation and the related RDRP goal. It is sustainable because of NIOSH's enabling authorities and the availability of intramural personnel and funding.

Progress: This activity has been critical to identifying and addressing the issue of flavorings-related lung disease. As already noted, the issue was originally identified through a technical assistance request. Observations from field investigations have motivated and informed laboratory investigations and efforts to develop authoritative recommendations. Since 2008, field work associated with HHEs and technical assistance requests has led to recognition of a broader spectrum of disease associated with flavorings exposure than initially identified, documentation of use of substitutes for diacetyl with similar toxicity, and improved approaches to exposure assessment and engineering controls.

Impact: Since 2008, seven HHEs have been completed in this area (for a full list of HHEs, see http://www.cdc.gov/niosh/topics/flavorings/additional.html). In addition, 11 peer-reviewed journal articles have been published, along with six review papers, book chapters, and editorials (see Appendix 4). Through the HHE process, RDRP has shared findings with and made recommendations to at least 21 companies directly (and has more widely disseminated information to the flavorings community through a website and NIOSH documents). These efforts have led to engineering controls, use of respirators, and in some cases institution of periodic spirometry. Substantial reductions in air concentrations of flavorings chemicals have resulted. NIOSH research has documented that, in the index plant where flavorings-related lung disease was first described, interventions have reduced adverse health effects (Kanwal 2011). Data from NIOSH field studies has been critical to the effort to develop of a criteria document and recommended exposure limit (REL; described as a separate activity below).

The state of California has been an important partner over the past several years. The California Division of Occupational Safety and Health (Cal/OSHA) and the California Department of Public Health (CDPH) developed a monitoring program (the Flavorings Industry Safety and Health Evaluation Program) after cases of flavorings-related lung disease were identified among workers in the state. RDRP provided Technical Assistance to CDPH, assisting with program development, spirometry quality review, and data sharing. Both Cal/OSHA and CDPH now have multiple flavorings postings on their websites and CDPH has guidance to help healthcare providers monitor the health of workers in companies that make flavorings. Cal/OSHA promulgated a diacetyl standard for California workers exposed to chemicals containing more than 1% diacetyl (Title 8 CCR section 5197). This rule specifies regulations for the use of engineering safeguards, respirators, and medical surveillance. In addition, the partnership has resulted in publications addressing exposure assessment, engineering controls, and medical monitoring of workers with spirometry.

In response to a request from the Occupational Safety and Health Administration (OSHA), NIOSH developed an agreement to provide OSHA with data from NIOSH HHEs so that OSHA could conduct analyses pertinent to OSHA regulatory activities. An outcome of NIOSH activities is that OSHA initiated a national emphasis program for flavoring manufacturers.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=4191

Future plans: Several HHEs in this area are in progress. They will continue efforts to document use of substitutes that are similar in structure to diacetyl, such as 2,3-pentanedione, 2,3-hexanedione, and 2,3-heptanedione. They will also seek to clarify the full range of health effects associated with flavoring exposure (such as restrictive lung disease). They may also offer the opportunity to implement and improve approaches to using longitudinal spirometry to identify excessive declines in lung function for the purposes of secondary prevention. In addition, a designed clinical and epidemiological investigation is being implemented to clarify the nature of, and risk factors for, restrictive lung disease associated with flavorings exposure. Partners involved in this investigation include investigators from the University of Cincinnati and from the California Department of Public Health.

Activity B: Conduct basic toxicology research, including inhalation toxicology studies, to better characterize the toxic potential and mechanisms of toxicity of diacetyl and other potentially toxic artificial flavorings.

Description/Relevance/Sustainability: Basic toxicology research has been critical to documenting that specific flavoring chemicals are respiratory toxins, to investigate mechanisms so that other potential respiratory toxins and the potential effects of combined exposures can be predicted, and to provide needed information for human risk assessment. This activity is critical in addressing the NA

recommendation and RDRP goal. It is sustainable, due to available personnel, research facilities, and funding.

Progress: There has been great progress in this area since 2008. Various *in vivo* models have been used to assess relative toxicities of alpha-diketone flavoring chemicals and 2,3 pentanedione has been documented to be a respiratory hazard. Flavoring dosimetry research led to development of a computational fluid dynamic-physiologically-based pharmacokinetic (PBPK) model of diacetyl. Investigation of mechanisms of flavoring-related lung disease has suggested a role for disordered metabolism by the enzyme dicarbonyl/L-xylulose reductase in pathogenesis. In addition, the ability of flavorings to act as sensitizing agents and to act on airways smooth muscle has been investigated.

Impact: From 2008 to the present, four peer reviewed papers and 11 abstracts have been published (see Appendix 4). These have had great influence, as they have documented that diacetyl and 2.3-pentanedione are causative agents for flavorings-related lung disease. This information, and PBPK modeling, has greatly influenced efforts to carry out risk assessment and develop a recommended exposure limit (see below). Unambiguous identification of diacetyl as a respiratory toxin has also influenced the actions of Cal/OSHA to regulate its use and of federal OSHA to carry out a special emphasis program related to use of diacetyl in flavorings manufacturing.

Future plans: Ongoing laboratory toxicology studies will include development of rapid screening tests to better identify flavorings that are respiratory toxins. Additional work will better clarify pathogenic mechanism(s) responsible for the respiratory toxicity of alpha-diketone flavorings so that structure-activity relationships can be determined. Investigations will also address the respiratory toxicity of powdered flavorings.

Activity C: Develop protective recommendations for exposure assessment and engineering controls in work settings using artificial flavorings; and provide regulators with…data and risk assessments they will need for worker protection over the long term.

Description/Relevance/Sustainability: This activity addresses the critical NIOSH function of providing authoritative recommendations for prevention of work-related disease. It involves the development of a NIOSH criteria document, which includes a quantitative risk assessment and REL for diacetyl and 2.3-pentanedione. It is critical part of responding to the NA recommendation and addressing RDRP goals. It is sustainable because of available data, personnel, and resources.

Progress: There has been excellent progress in this area. A cross-Institute, multidisciplinary team was assembled that conducted a thorough scientific review of diacetyl and 2,3-pentanedione toxicity, the basis for hazard identification. In addition, a risk assessment using data derived from workplace investigations (HHEs) and laboratory-based toxicology studies was developed. The draft criteria document was posted for public comment, discussed at a public meeting, and has undergone peer review.

Impact: The draft document, *Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-Pentanedione* is posted on the NIOSH website. It can be found at: http://www.cdc.gov/niosh/docket/review/docket245/ In addition to proposed RELs, the document contains comprehensive prevention recommendations. Innovative research needed to enable the risk assessment described in the document was conducted in collaboration with OSHA. It developed a method to correct historical diacetyl exposure measurements that had been made using a method that systematically underestimated exposures in the presence of high humidity (Cox-Ganser 2011). Also, a risk assessment evaluating relative potency of 2,3-pentanedione and diacetyl has been reported in abstract

form in collaboration with an investigator from the National Institute for Environmental Health Sciences - National Toxicology Program [Dankovic & Morgan 2012].

Future plans: Edit draft criteria document in response to public comments and peer review. The document is projected to be finalized in 2013.

Chronic Obstructive Pulmonary Disease (COPD)

Text from NA Report: "In terms of chronic obstructive pulmonary disease (COPD), understanding the contribution of occupational exposures is difficult. To understand this issue, the evaluation committee strongly recommends that, for planning preventive strategies, the RDRP continue to support population-based studies of associations between occupational exposures and COPD to better define groups of workers at greatest risk." (p134)

Responsive RDRP Goal: Prevent and reduce work-related COPD.

Status: In progress

Background: About 12 million people in the U.S. have COPD, which includes emphysema and chronic bronchitis. In 2009, COPD caused 137,353 deaths in the U.S. and was the 3rd leading cause of death. Many people know that COPD is caused by cigarette smoking. About 75% of cases can be attributed to smoking. Fewer people are aware that work-related exposures are also an important cause of COPD. Based on a comprehensive review of the literature, the American Thoracic Society has estimated that about 15% of COPD cases can be attributed to work. Thus, work-related COPD is a major health issue. To address this issue, RDRP has conducted investigations to estimate the burden of work-related COPD and risk factors for its development. In addition, RDRP has conducted investigations to improve early detection of work-related COPD, in particular through longitudinal pulmonary function testing with spirometry to detect excessive lung function decline and prevent COPD development. These investigations provide a necessary conceptual basis for development of appropriately targeted, effective prevention efforts.

External Factors: As is the case for many work-related chronic diseases, it is difficult to estimate the burden and distribution of work-related COPD. COPD has a long latency and thus may not be recognized as work-related if onset occurs after leaving a job or entering into retirement. Also, because tobacco smoking is an important risk factor, COPD is often attributed to smoking and other potential causes are not considered as possible etiologies. There is a relative lack of ongoing national morbidity or mortality data that would provide information on the prevalence or incidence of COPD by industry or occupation. Such data would facilitate ongoing surveillance assessing for excess burden of COPD in particular occupations or industries.

Implementation of Recommendation

Activity A: Conduct surveillance and epidemiological studies to assess the extent, severity, and burden of work-related COPD and identify industries and occupations associated with COPD

Description/Relevance/Sustainability: This activity involves intramural and extramural work to document burden and risk factors for work-related COPD. For that purpose RDRP used large population-based studies, such as the National Health and Nutrition Examination Survey (NHANES). Other studies have examined worker populations with specific exposures such as coal mine dust, beryllium, endotoxin, World Trade Center (WTC) dust, etc. Both types of investigations are directly responsive to the NA recommendation. They are also responsive to the relevant RDRP goal. They are sustainable, due to availability and allocation of intramural personnel and resources and extramural funding.

Progress: Since 2008, a substantial amount of research has been conducted and published (Appendix 5). In addition, a substantial body of research has been initiated and is in progress. Collaborations have been established with large national studies. For example, RDRP is contributing to the current round of NHANES in collaboration with other parts of CDC, primarily the National Center for Health Statistics (NCHS). There is

a history of important impacts through this collaboration. RDRP was deeply involved in NHANES III, which collected data from 1987-1994. NIOSH led the effort to collect spirometry data from participants. The major prediction equation used today in clinical settings to determine if results of spirometry are normal or abnormal (the "Hankinson equation") was published in 1999 using that data. Analysis of data from that round of NHANES provided important insights into the burden of work-related COPD and obstructive lung disease in general. To study work-related COPD risk in the current population, RDRP developed and submitted a proposal to NCHS to include spirometry and information about occupation and industry in the current round of NHANES. The proposal was accepted, and RDRP has been providing NHANES with spirometers and other necessary equipment, technician training, and quality control. NIOSH is also coding questionnaire data about longest-held occupation and industry. RDRP has also established a group to evaluate the NHANES data for prevalence of COPD, work-related and non-work-related risk factors, and risk attributable to work.

Another example of progress is a study using data obtained from the Multi-Ethnic Study of Atherosclerosis (MESA). This study was initiated in 2000 and had the primary goal of investigating the prevalence and progression of subclinical cardiovascular disease. However, it provides an opportunity to investigate work-related COPD, since it collected information about occupation and industry and evaluated participants with spirometry and high resolution computed tomography of the chest (HRCT; this test can be used to detect lung destruction by emphysema). MESA study data was obtained, industry and occupation information coded, a job-exposure matrix (JEM) for COPD developed, and a manuscript on work-related risk factors for HRCT-detected emphysema and spirometry-detected COPD is in preparation.

Impact: Since 2008, RDRP has published numerous peer-reviewed research reports providing information on associations between work and COPD (Appendix 5). This work has been accomplished by intramural and extramural investigators. Examples include a case control study identifying the exposures most strongly associated with COPD as diesel exhaust, irritant gases and vapors, mineral dust, and metal dust (Weinmann 2008). The validity of the JEM used in this study was documented in a separate publication (Graziani 2012). A study using National Health Interview Survey (NHIS) data found the overall population attributable fraction of work-related COPD to be 12.2% for industry and 17.4% for occupation (Bang 2009). Another study using NHIS data documented smoking rates in various industries and occupations (MMWR 2011). Research using data from the Atherosclerosis Risk in Communities Study (a longitudinal cohort study) also identified occupations at risk for COPD symptoms (Mirabelli 2012). Examples of specific exposures found to be associated with COPD have included coal mine dust (Kuempel 2009), beryllium (Schubauer-Berigan 2010, 2011), agricultural dust (Schenker 2009), and cotton dust/endotoxin (Shi 2010). In addition, numerous publications have documented the still-evolving pattern of chronic lung disease associated with WTC dust. RDRP engaged with other parts of CDC and external experts to produce the report *Public Health Strategic Framework for COPD Prevention* in 2011: http://www.cdc.gov/copd/pdfs/Framework_for_COPD_Prevention.pdf .

Future plans: RDRP will analyze current NHANES data to evaluate current associations between work and COPD and to determine attributable risks; and to establish industry- and occupation-specific trends in tobacco use since NHANES III. RDRP will also use current NHANES data to conduct research into spirometry reference equations. One aspect of this will be to explore developing a reference equation for Asian-Americans, who were not addressed by the 1999 "Hankinson equation" (Asian-Americans were oversampled in the current round of NHANES). RDRP will conduct further analyses of the MESA data using the HRCT-based emphysema outcome in relation to occupational exposure. Investigators supported by extramural funds will investigate risks for COPD associated with construction work, post-Katrina related airborne exposures, cotton dust/endotoxin exposures (including impact of genetic polymorphisms), and WTC dust exposures. We will attempt to identify other population-based data that include spirometry or questions on doctor-diagnosed COPD that might offer opportunity for informative analyses.

Activity B: Improve tools such as longitudinal spirometry and respiratory questionnaires for early detection of occupationally-related COPD

Description/Relevance/Sustainability: Through life, pulmonary function (as measured by spirometry) typically increases as the individual grows, reaches a plateau, and then declines. Decline usually sets in during the 20s or 30s. Excessive rates of decline over a long enough period of time (typically many years for COPD) can result in spirometry that is abnormal for age, height, race, and gender (the key variables used in equations that predict normal values). Thus, excessive decline in lung function can potentially be used to identify those at increased risk for progression to COPD before their pulmonary function drops to a level that causes clinical disease. Identification of those with excessive loss of lung function is not straightforward, particularly during the first 4-7 years of follow up. This is because variability in measurement ("noise") is typically greater than actual decline ("signal"). RDRP has focused great effort on improving the quality of spirometry, which is a technically challenging test to perform, and in developing approaches to identifying those who have declines in lung function that exceed expected decline, taking into consideration measurement variability. RDRP has also worked to demonstrate how this information can be used for targeted health protection and health promotion activities. Improving detection of COPD is responsive to the NA recommendation and to the relevant RDRP goal. It is sustainable due to allocation of intramural personnel and resources.

Progress: RDRP has engaged in a number of activities to improve occupational spirometry and apply results to the prevention of COPD. NIOSH has the authority to approve training programs for spirometry technicians. Thus, RDRP has maintained and improved a spirometry course certification program that provides technician training materials and approves training courses: http://www.cdc.gov/niosh/topics/spirometry/training.html. NIOSH has also conducted research, using various databases of periodic spirometry monitoring to develop methods for obtaining periodic spirometry data, analyzing it, and using the information for prevention.

Impact: RDRP has made or encouraged a number of enhancements to spirometry training courses. Course approvals have been changed from indefinite to five year terms. Also, technicians are now required to complete refresher courses every five years. Online courses are now available for refresher training: http://www2a.cdc.gov/drds/spirometry/schedule.asp. A number of up to date training materials have been developed and made available to the public. A spirometry training manual can be downloaded from the NIOSH website. A popular product developed during 2011 was a poster intended for display in spirometry laboratories as a handy reference for the spirometry technician, which illustrates spirometry problems and how to rectify them. Fifteen spirometer manufacturers are committed to sending one of these posters with every spirometer that they ship and 60,000 posters have already been disseminated. Currently, it is available in five languages (English, Spanish, Portuguese, Indonesian, and Chinese), with plans for six more translations (Arabic, French, Italian, Russian, Thai, and Turkish): http://www.cdc.gov/niosh/docs/2011-135/. Also in 2011, OSHA and NIOSH jointly developed two information sheets. One provides information to employers to help them in establishing high-quality spirometry surveillance programs: http://www.osha.gov/Publications/osha3415.html. Another is targeted to workers and explains the test: http://www.osha.gov/Publications/osha3418.html. An article about these two OSHA-NIOSH products appeared in the May 10, 2011 issue of *Science in the News* (the American College of Occupational and Environmental Medicine's official magazine) and was the 3rd most accessed of 2011.

A number of publications address spirometry and COPD prevention (Appendix 5). Studies conducted by Hnizdo *et al* have documented sophisticated approaches to monitor longitudinal data quality and precision and methods that enhance the precision of the identification of those with excessive decline

in lung function. Data from the Copenhagen City Heart Study was used to document that excessive rate of decline in forced expiratory volume in one second (FEV1; a measurement obtained from spirometry) is associated with increased morbidity and mortality, even if the FEV1 has not declined sufficiently to leave the normal range (Baughman 2011). Software has been posted on the NIOSH website to help surveillance programs evaluate longitudinal data and also to monitor the quality of their data: http://www.cdc.gov/niosh/topics/spirometry/spirola.html. Partners have been engaged to demonstrate the usefulness of using accelerated pulmonary function decline to target secondary prevention, either to non-occupational causes (smoking, weight gain, sedentary lifestyle) or occupational causes (hazardous exposures).

Future plans: Maintain high quality spirometry training courses through site visits and re-certification. Provide additional training materials, including a spirometry training video. Continue to work with partners in the construction industry and firefighting to demonstrate usefulness of longitudinal spirometry in COPD prevention through targeted health promotion for non-occupational causes and health protection for occupational causes. Maintain and improve longitudinal spirometry software (SPIROLA) as a tool available for evaluating populations over time.

Work-Related Asthma

Text from NA Report: "Because the contribution of occupational exposures to the burden of adult asthma is high, work in pursuit of the four WRA subgoals can have a potentially large impact on improved occupational safety and health among the U.S. workforce." (p134)

Responsive RDRP Goal: Prevent and reduce the full range of work-related asthma (WRA), including work-exacerbated asthma; occupational asthma; and irritant-induced asthma

Status: In progress

Background: WRA is the most frequently diagnosed occupational respiratory disorder in many industrialized countries, including the U.S. About 18.7 million adults in the U.S. currently have asthma. The American Thoracic Society estimates that about 15% of these adults have asthma attributable to occupational factors, totaling about 2.8 million people. About 23% of adults with asthma experience exacerbations of their asthma related to work. Thus, WRA is a major problem. WRA can be divided into two broad categories, new-onset asthma that is caused by exposures at work and work-exacerbated asthma (WEA) that is not caused by work, but is worsened by exposures at work. New-onset asthma can be divided into occupational asthma (OA), typically caused after a latent period by sensitizing workplace asthmagens, and irritant-induced asthma (sometimes called "reactive airways dysfunction syndrome"). Sensitizing workplace asthmagens can either be low molecular weight (LMW) or high molecular weight (HMW) agents. LMW agents are generally small reactive chemicals such as isocyanates. For many LMW agents, including isocyanates, the mechanism of action for causation of asthma is not fully understood. HMW agents are generally proteins that elicit allergic immunoglobulin E responses in a fashion similar to common environmental allergens such as ragweed or cat allergen. Since 2008, RDRP has conducted a wide range of activities to address the important challenge of WRA. These extend upon activities previously reported to the NA, including characterizing the burden of WRA through surveillance; addressing LMW agents such as isocyanates and HMW agents such as latex; and addressing asthma related to indoor environmental quality issues such as dampness and mold. RDRP is known for its work in this area and has contributed to influential statements on WRA by the American Thoracic Society (Henneberger 2011) and on management of WRA by the European Respiratory Society (Bauer 2012).

External Factors: It is difficult to track the burden and distribution of WRA. In the clinical setting, work-related factors are often not explored or documented. At a population level, there is a relative lack of ongoing national morbidity and mortality data that provides information about prevalence of asthma in different industries and occupations. Such data would facilitate ongoing surveillance to evaluate for excess burden of asthma in particular occupations or industries.

Implementation of Recommendation:

Activity A: **Assess the extent, severity, burden, and risk factors for WRA and approaches to prevention across a broad range of industries and occupations**

Description/Relevance/Sustainability: Surveillance efforts for work-related respiratory disease in general have already been presented in the section on surveillance. This section provides additional information about efforts to assess the burden of WRA across multiple industries and occupations. Activities that address a single occupation or industry are discussed separately below. These efforts are directly relevant to recommendations of the NA committee and to the RDRP goal. They are sustainable due to allocation of funding and personnel.

Progress: RDRP has leveraged several large studies to carry out this work. For example, RDRP investigators have partnered with CDC's National Center for Environmental Health (NCEH) to add questions about WRA to the BRFSS Asthma Call-back Survey (ACBS) which collects information from adults who report an asthma diagnosis. RDRP is collaborating with NCHS in the NHANES study during the years 2007-2012. The program provides administrative and technical support for NHANES to conduct spirometry, provides quality assurance for spirometry, and adds questions regarding work to allow for the development of a job exposure matrix to assess risks for respiratory disease. RDRP has partnered with other parts of NIOSH and with CDC's National Center for Health Statistics (NCHS) to add questions about WRA to an occupational health supplement to the National Health Interview Survey (NHIS). RDRP has entered into partnership with NCHS to include questions relevant to WRA in the National Ambulatory Medical Care Survey. Data collection is in progress. This will provide information on physician compliance with NIH guidelines on diagnosis and management that are relevant to WRA when caring for adults with asthma. In addition, much state-based surveillance has focused on WRA, as was previously noted in the surveillance section.

Impact: ACBS has been extremely informative. For example, across 38 states and the District of Columbia, the overall proportion of current asthma identified by a health professional as WRA was nine percent. Proportions of WRA were highest among persons aged 45-64 years (12.7%), blacks (12.5%), and persons of other races (11.8%)(Knoeller 2012). As a group, individuals with WRA have worse asthma outcomes, more depression and worse quality of life than those with asthma with no work relation (Knoeller 2012, Mazurek 2012). Those with WRA often have financial barriers to care (Knoeller 2011). The ACBS also provides estimates that 47.5% of ever-employed adults with asthma describe their asthma as being caused or exacerbated by workplace exposures (Knoeller 2011). Of these adults, only 17.6% are diagnosed with WRA by a health professional (Knoeller 2012). Data have recently become available for the NHIS-Occupational Health Supplement. It has already been used to document exposures relevant to WRA (Calvert 2012). For example, the prevalence of frequent occupational exposure to vapors, gas, dust, or fumes at respondents' longest-held jobs was 25.0%. The highest prevalence rates were seen in workers employed in construction, mining and installation, maintenance and repair. The prevalence of frequent workplace exposure to second hand smoke among non-smoking workers in the previous year was 10%. The NHIS-Occupational Health Supplement has also documented that only one in seven employed adults with asthma discuss the possible role of workplace exposures in their asthma with their health professional, identifying potential for improvement in care (Mazurek 2012). National Ambulatory Medical Care Survey data, when it is available, will provide additional information about WRA-related quality of care. Another notable RDRP effort is the Prevention of Occupational Asthma website http://www.cdc.gov/niosh/topics/asthma/occasthmaprevention.html . This website provides easy access to the world literature on prevention of occupational asthma across the full range of hazards, occupations, and industries. It was visited 5352 times in the last 12 months.

Future Plans: RDRP will continue to leverage its resources by collaborating with large national surveys. It will analyze additional data from the ACBS and NHIS-Occupational Health Supplement. Data from the National Ambulatory Medical Care Survey will be analyzed to better understand quality of care of adults with asthma. The current round of NHANES will contain information about usual occupation, industry, asthma status, and objective measurement of spirometry and exhaled nitric oxide (a marker of airways inflammation in asthma). Thus, it will also provide an excellent opportunity to evaluate burden and severity of asthma in the context of occupational risk factors. In addition, the Prevention of Occupational Asthma website will continue to be maintained.

Activity B: Identify, document, and characterize emerging causes of WRA, including novel host factors, novel occupational exposures, and irritant inhalation exposures encountered during natural or man-made disasters

Description/Relevance/Sustainability: Potential and emerging causes of WRA are identified through population-based surveillance, HHEs, case-based surveillance conducted by states with NIOSH technical support, stakeholder input, scientific literature, etc. Documenting and characterizing these is responsive to guidance from the NA. Note that WRA related to indoor air quality will be discussed separately. This activity is sustainable due to ongoing availability of resources and personnel.

Progress: There are numerous examples of progress. Highlights include the following: Studies are evaluating WRA in healthcare workers and evaluating relationships to exposures such as cleaners, disinfectants and other known asthmagens in healthcare. These have involved development of novel methods for assessing exposures such as volatile organic compounds (VOCs) and quaternary ammonium compounds and in reconstructing exposures using job-exposure matrices (JEMs). They are being pursued in partnership with the Service Employees International Union and the Veterans Administration. In partnership with the National Institute for Environmental Health Sciences, RDRP investigators are collaborating to study asthma in Agricultural Health Study (AHS) participants, who are exposed to LMW agents such as pesticides and HMW agents such as animal dander, grain dust, mites, etc. HHEs have triggered work evaluating diverse, potentially asthmagenic exposures such as chloramines in poultry facilities and swimming pools; flour-related allergens in baking; and soy allergen in a soy processing plant. Based on concerns about the safety of the substitute ortho-phthaldehyde (OPA) for the decontaminating agent glutaraldehyde, an exposure assessment method was developed and animal studies done showing it to induce T helper 2 (allergic-type) immune responses.

Impact: Publications address pesticide exposure and asthma (Hoppin 2009) and sensitization to allergens in AHS participants (Endres 2012); evaluation of associations between cleaners, disinfectants, and asthma in healthcare workers (Arif 2012); documentation of the effectiveness of reducing glove-related latex exposures in healthcare (Kelly 2011); evaluation of IgE-sensitization to flour-related allergens in bakery workers (Page2010), evaluation of asthma in insect-rearing workers for two different orders of insects (Lepidoptera and Diptera)(Suarthana 2012); assessing airways symptoms and inflammation in wild land fire fighters [this study was cited by the National Fire Protection Association as a basis for developing specifications for respiratory protection for wild land fire fighters](Gaughan 2009); assessing airways symptoms and documenting beneficial impact of disposable respirator use during recovery from hurricanes Katrina and Rita (Cummings 2008); assessing asthma after WTC dust exposure (numerous); documenting the relation between dust exposure and work-related asthma-like symptoms in smelters (Soyseth 2012); measuring airborne isocyanate exposures in auto body shops (Reeb-Whitaker 2012); assessing impact of chloramine exposures in poultry workers (Chen 2012) and pool lifeguards (Chen 2008, Dang 2010); assessing sensitization to soy allergens and asthma in soy processing plant workers (Gaughan 2009, Cummings 2010, Green 2011); developing methods to assess exposure to OPA (Tucker 2008) and documenting OPA's ability to be a sensitizer in mice after topical application (Anderson 2010) and inhalation (Johnson 2011). This work has touched on many causes of WRA, documenting their adverse effects and the need to prevent these causes of asthma.

Future Plans: RDRP will complete two studies of asthma in healthcare workers that are already in progress. RDRP will continue to collaborate with AHS in analyzing data from its third[t] round of data collection and from an AHS asthma case-cohort study that will allow a more in-depth investigation of the causes of asthma in AHS participants. RDRP will continue to be opportunistic, conducting HHEs and following up on potential emerging causes of WRA.

Activity C: Evaluate the impact of indoor air quality on WRA and the effectiveness of building remediation in preventing WRA associated with poor indoor air quality

Description/Relevance/Sustainability: In 2009, a work group assembled by the World Health Organization (WHO) authored authoritative *WHO guidelines on indoor air quality: dampness and mould*. This document relied in part on research conducted by RDRP. It found sufficient epidemiological evidence to show that the occupants of damp or moldy buildings are at increased risk of respiratory symptoms, respiratory infections and exacerbation of asthma and some evidence suggesting increased risks of allergic rhinitis and asthma. It was noted that few intervention studies were available, but available results showed that remediation of dampness could reduce adverse health outcomes: http://www.euro.who.int/en/what-we-do/health-topics/environment-and-health/air-quality/policy/indoor-air-quality/biological-indoor-air-pollutants-dampness-and-mould. Indoor dampness and mold are important hazards in many workplaces, including non-industrial workplaces such as office buildings and schools. Complaints related to indoor air quality are the most frequent resulting in HHE requests. Thus, the impact of indoor air quality, including impact of dampness and mold, on WRA remains an important and relevant area of investigation. Investigations in this area are sustainable, due to the availability of resources and personnel to work in this important area.

Progress: Since 2008, RDRP has completed a multi-year longitudinal evaluation of a large office building with significant dampness and mold problems that was conducted in partnership with the University of Connecticut. RDRP has partnered with the Maine Department of Education to evaluate relationships between dampness and ventilation problems in the public schools and adverse health effects in occupants. It has partnered with the Philadelphia School District and the staff of the Philadelphia Federation of Teachers Union and Health and Health and Welfare Fund to pilot a tablet computer-based dampness and mold assessment tool to prioritize buildings for repair and remediation. Laboratory efforts are evaluating novel indoor air contaminants such as mycotoxins and oxidation products of volatile organic compounds (VOCs) from cleaning agents. Based on work published by RDRP, an investigator participated in an influential Cochrane review of the effectiveness of remediation on health effects related to indoor dampness and mold.

Impact: The longitudinal study of a large office building described above led to multiple publications. It documented that those building occupants with rhinosinusitis symptoms and higher levels of fungal exposure were at greater risk for subsequent development of asthma symptoms (Park 2012). Efforts to remediate the building failed to correct dampness problems and were associated with lack of improvement in level of fungal contamination (Cho 2011) and lack of improvement in respiratory health of occupants (Iossifova 2011). There were a number of laboratory-based achievements. These included development of molecular methodologies to assess fungal diversity in environmental samples (Rittenour 2012); development and evaluation of methodologies for fungal air sampling (Yamamoto 2011, Han 2011); production of monoclonal antibodies against *Stachybotrys* hyphal antigens (Nayak 2011); and validating the best method for extracting 1 → 3-β-glucan from dust samples that resulted in correlation of 1 → 3-β-glucan levels with *in vivo* potency of the dust samples for inducing inflammation after intrapulmonary instillation (Young 2011). Indoor air chemistry-related publications documented that a persistent troublesome odor in an office was related to VOCs (possibly alcohols) released from carpet adhesive and/or backing and poor ventilation (Ceballos 2012); and evaluated the potential of cleaning agent-related VOCs and their oxidation products as potential irritants and sensitizers (Ham 2011, Waring 2011, Springs 2011, Forester 2011, Anderson 2012). An authoritative Cochrane review described the need for better evidence of impact of remediation on adverse health effects related to dampness and mold (Sauni 2011).

Future Plans: RDRP will complete studies evaluating for associations between indoor dampness and mold and adverse health effects in the Maine Public Schools. RDRP will complete its demonstration project of the electronic dampness and mold assessment tool in the Philadelphia Public Schools. Based on feedback from users, improvements will be made to the tool and it will be made available on the NIOSH website. RDRP will study associations between adverse health effects and novel indoor chemical and microbial-derived agents. RDRP will complete and disseminate a NIOSH Alert providing up to date information about indoor dampness and mold.

Activity D: Develop and implement demonstration projects that address the role of screening and surveillance for WRA in occupational settings

Description/Relevance/Sustainability: RDRP, the American Chemistry Council and participating facilities are collaborating to demonstrate a medical monitoring program evaluating workers at all toluene diisocyanate production facilities in the U.S. The project also characterizes exposures in various jobs and tasks. This is relevant to the NA recommendation to pursue such work and the RDRP goal. It is sustainable until completion at minimal cost to RDRP due to active collaboration of partners.

Progress: Working with partners, a medical monitoring protocol was established and deployed for five years. Data collection was completed June 30, 2012.

Impact: Nearly 200 employees have had regular medical monitoring using initial and periodic questionnaires and spirometry since 2007.

Future plans: RDRP and partners will analyze data to evaluate the usefulness of the monitoring program. Results will be disseminated as appropriate to stakeholders to assist in prevention of WRA.

Activity E: Develop improved tools for detection of allergic sensitization to low molecular weight allergens such as isocyanates or high molecular weight allergens such as mold allergens.

Description/Relevance/Sustainability: Work relevant to fungal-derived agents was described above in the section on indoor air. This section will describe work relevant to diisocyanates. Exposure to diisocyanates results in formation of diisocyantate-protein adducts. Research has been conducted to characterize these adducts and raise monoclonal antibodies against them. These monoclonal antibodies are tools that can be used to develop enzyme-linked immunosorbant assays, which, in turn, can be used for biomonitoring and/or determination of protein-binding sites. This work is relevant to the NA recommendations and is sustainable due to the availability of intramural resources and personnel.

Progress: Multiple monoclonal antibodies have been produced against 2,4- and 2,6- toluene diisocyanates and methylene diphenyldiisocyanate protein adducts. Monclonal antibody specificity has been assessed and a patent application filed. Adduction sites of diisocyanates on human albumin and hemoglobin have been identified using ultra-high performance liquid chromatography-quadrapole-time of flight mass spectrometry. Influence of the body's antioxidant thiols on protein adduction has been assessed in collaboration with Yale researchers.

Impact: Biomonitoring through the use of anti-diisocyanate-monoclonal antibodies may aid in prevention; and the results of adduct mapping using monoclonal antibodies may be useful for early detection and intervention for sensitized workers. Six peer-review reports, an abstract, and a patent have resulted (Appendix 6). Anti-diisocyanate monoclonal antibodies have been disseminated to one academic institution and a chemical company that uses diisocyanates.

Future plans: Anti-diisocyanate monoclonal antibodies will be made available to new partners in academia and industry. Proteomic tools will be applied to mechanistic studies of asthmagenesis.

Appendix 1

RDRP Strategic Goals, 2012

Strategic, Intermediate, and Output Goals:

Strategic Goal 1 (09PPRDRSG1):
Prevent and reduce work-related airways diseases.
It should be noted that surveillance, education, communication, information dissemination, and providing support to standard-setting and regulatory groups are all critical to achieving outcomes.

Intermediate Goal (09PPRDRIG1.1): prevent and reduce the full range of work-related asthma (WRA), including work-exacerbated asthma; occupational asthma; and irritant-induced asthma.

Activity/Output Goal (09PPRDRAOG1.1.1): assess the extent, severity, burden, and risk factors for WRA and approaches to prevention across a broad range of industries and occupations.

Activity/Output Goal (09PPRDRAOG1.1.2): develop improved tools for detection of WRA by questionnaire or ambulatory spirometry.

Activity/Output Goal (09PPRDRAOG1.1.3): develop improved tools for detection of allergic sensitization to low molecular weight allergens such as isocyanates or high molecular weight allergens such as mold allergens.

Activity/Output Goal (09PPRDRAOG1.1.4): identify, document, and characterize emerging causes of WRA, including novel host factors, novel occupational exposures, and irritant inhalation exposures encountered during natural or man-made disasters.

Activity/Output Goal (09PPRDRAOG1.1.5): evaluate the impact of indoor air quality on WRA and the effectiveness of building remediation in preventing WRA associated with poor indoor air quality.

Activity/Output Goal (09PPRDRAOG1.1.6): develop and implement demonstration projects that address the role of screening and surveillance for WRA in occupational settings.

Activity/Output Goal (09PPRDRAOG1.1.7): conduct basic research to better define the mechanisms of action of low molecular weight sensitizers and irritants capable of inducing WRA and to better characterize high molecular weight occupational allergens and their health effects.

Intermediate Goal (09PPRDRIG1.2): prevent and reduce work-related COPD.

Activity/Output Goal (09PPRDRAOG1.2.1): conduct surveillance and epidemiological studies to assess the extent, severity, and burden of work-related COPD and identify industries and occupations associated with COPD.

Activity/Output Goal (09 PPRDRAOG1.2.2): conduct systematic population-based studies to better define groups of workers at greatest risk of COPD and guide development of preventive strategies.

Activity/Output Goal (09PPRDRAOG1.2.3): improve tools such as longitudinal spirometry and respiratory questionnaires for early detection of occupationally-related COPD.

Activity/Output Goal (09 PPRDRAOG1.2.4): develop and improve methods for collecting, analyzing, and responding to the results of longitudinal pulmonary function testing to optimize identification and secondary prevention for individuals at risk of developing severe COPD.

Activity/Output Goal (09 PPRDRAOG1.2.5): promote the implementation of longitudinal pulmonary function testing in the workplace for surveillance and intervention in populations at risk for fixed airways obstruction.

Activity/Output Goal (09PPRDRAOG1.2.6): study associations between irritant inhalation exposures during disasters, such as dust at the site of the World Trade Center (WTC) collapse, and development of obstructive lung disease (this objective overlaps with asthma prevention, since many affected individuals have reactive airways disease; and potentially will overlap with other long-term effects of WTC-related exposures).

Intermediate Goal (09PPRDRIG1.3): prevent and reduce flavorings-induced obstructive lung disease, including bronchiolitis obliterans.

Activity/Output Goal (09PPRDRAOG1.3.1): conduct surveillance, epidemiological studies, and field studies to identify the full range of food production industries at risk for flavorings-induced lung disease.

Activity/Output Goal (09PPRDRAOG1.3.2): develop and improve sampling and analytical methods for assessing exposure to diacetyl and other artificial flavorings.

Activity/Output Goal (09PPRDRAOG1.3.3): develop protective recommendations for exposure assessment and engineering controls in work settings using artificial flavorings; disseminate information to improve recognition of flavorings-induced lung disease by a range of groups, including clinical practitioners, public health officials, facilities using artificial flavorings, and workers using artificial flavorings; disseminate information and encourage health care providers to report cases of flavoring-induced lung disease to state health departments and NIOSH.

Activity/Output Goal (09PPRDRAOG1.3.4): provide regulators with information needed to address current requests for Emergency Temporary Standards for diacetyl and the data and risk assessments they will need for worker protection over the long term.

Activity/Output Goal (09PPRDRAOG1.3.5): conduct basic toxicology research, including inhalation toxicology studies, to better characterize the toxic potential and mechanisms of toxicity of diacetyl and other potentially toxic artificial flavorings.

Strategic Goal 2 (09PPRDRSG2):
Prevent and reduce work-related interstitial lung diseases.
It should be noted that surveillance, education, communication, information dissemination, and providing support to standard-setting and regulatory groups are all critical to achieving outcomes.

Intermediate Goal (09PPRDRIG2.1): prevent and reduce coal mine dust-induced respiratory diseases, with primary focus in this intermediate goal on CWP and PMF.

Activity/Output Goal (09PPRDRAOG2.1.1): improve technologies for dust assessment and dust control in coal mining. Provide technical guidance for the use of a personal dust monitor for real-time assessments of dust exposure.

Activity/Output Goal (09PPRDRAOG2.1.2): identify state-of-the-art technologies for controlling coal mine dust exposures and transfer this information to industry through a series of regional dust control workshops by October 2012.

Activity/Output Goal (09PPRDRAOG2.1.3): perform x-ray surveillance for CWP to monitor the extent and severity of the problem. Investigate the nature and causes of geographic "hot spots" of pneumoconiosis, in part by completing a comprehensive program of mine-site sampling to assess the impact of geology, control technology and mining practices. Survey mines in hot-spot and non-hot-spot areas of the coal fields to assist in identifying factors associated with rapid disease development and progression. In addition, conduct surveillance of surface miners for pneumoconiosis

Activity/Output Goal (09PPRDRAOG2.1.4): engage Mine Safety and Health Administration (MSHA) in a dialogue with the aim of adopting the NIOSH – REL (1.0 mg/m^3) as the actual PEL for coal mine dust exposure. As the enactment of such a PEL would be solely the domain of MSHA, we have no control over the process or timeframe.

Activity/Output Goal (09PPRDRAOG2.1.5): perform studies and develop updated recommendations for chest imaging of pneumoconiosis that allow implementation of digital imaging for classification of chest radiographs using the International Labour Office classification system. Transition NIOSH's mandated surveillance activities, including the B reader certification program, to use of digital chest imaging.

Intermediate Goal (09PPRDRIG2.2): prevent and reduce silica-induced respiratory diseases, with primary focus in this intermediate goal on silicosis.

Activity/Output Goal (09PPRDRAOG2.2.1): conduct hazard surveillance to track silica exposures and seek new or overlooked sources of silica exposure to workers.

Activity/Output Goal (09PPRDRAOG2.2.2): reduce hazards associated with abrasive silica sand blasting by evaluating the relative respiratory toxicities of silica vs. abrasive blasting alternatives such as coal slag, garnet, steel grit, crushed glass, and specular hematite.

Activity/Output Goal (09PPRDRAOG2.2.3): develop, improve and validate sampling and analytical methods for assessing exposures to silica.

Activity/Output Goal (09PPRDRAOG2.2.4): develop mining control technologies to reduce or eliminate silica exposure, which would include dust reduction or particle coating. Transfer information on these silica control technologies to the metal/non-metal mining industry through a series of regional workshops.

Activity/Output Goal (09PPRDRAOG2.2.5): develop and improve control technologies to reduce or eliminate silica exposures across a range of occupational settings where silica is a known problem (mining, construction, abrasive blasting, foundries, dental laboratories, etc.) and in new occupational settings where silica exposure may appear as an emerging problem.

Activity/Output Goal (09PPRDRAOG2.2.6): develop and validate approaches to early detection for silicosis such as new approaches to chest imaging and assessment of biomarkers associated with silica exposure and interstitial lung disease.

Intermediate Goal (09PPRDRIG2.3): prevent and reduce "fiber"-induced respiratory diseases.

Activity/Output Goal (09PPRDRAOG2.3.1): Finalize a document that identifies current research gaps and priorities in the area of respiratory diseases caused by inhalation exposure to asbestos and other elongated mineral particles and has had the benefit of extensive and public expert and stakeholder review, including a review by the National Academies (Note: completed in 2011).

Activity/Output Goal (09PPRDRAOG2.3.2): develop improved sampling and analytical methods for assessing exposure to asbestos and other elongated mineral particles.

Activity/Output Goal (09PPRDRAOG2.3.3): conduct hazard surveillance to document workers, job tasks, and industries in which workers are exposed to various types of elongated mineral particles, including elongated cleavage fragments of amphibole minerals.

Activity/Output Goal (09PPRDRAOG2.3.4): conduct epidemiological investigations to better characterize the relationships between exposures to asbestos and other elongated mineral particles, including elongated cleavage fragments of amphibole minerals, and health effects such as interstitial lung disease, lung cancer, and mesothelioma.

Activity/Output Goal (09PPRDRAOG2.3.5): perform basic toxicologic research to elucidate the important determinants of toxicity for asbestos fibers and other elongated mineral particles and to improve the ability to predict the toxic potential of natural and man-made inorganic fibers.

Activity/Output Goal (09PPRDRAOG2.3.6): develop and publish a NIOSH Alert on flock and the flock workers' lung.

Intermediate Goal (09PPRDRIG2.4): prevent and reduce beryllium sensitization and chronic beryllium disease.

Activity/Output Goal (09PPRDRAOG2.4.1): evaluate the effectiveness of a comprehensive preventive program that includes reduction of skin exposures at a copper-beryllium alloy in reducing immunological sensitization to beryllium and chronic beryllium disease.

Activity/Output Goal (09PPRDRAOG2.4.2): evaluate the effectiveness of a comprehensive preventive program that includes reduction of skin exposures at a beryllium manufacturing facility in reducing immunological sensitization to beryllium and chronic beryllium disease.

Activity/Output Goal (09PPRDRAOG2.4.3): perform a cohort study assessing the longitudinal development of immunological sensitization to beryllium and chronic beryllium disease in workers at a beryllium oxide/ceramics plant over an eleven-year follow-up period.

Activity/Output Goal (09PPRDRAOG2.4.4): develop, refine and validate improved methods to assess exposure to beryllium; and determine whether complex exposure metrics taking estimated dissolved beryllium dose and dermal exposure into account are better predictors of adverse health effects than simple mass-based exposure metrics.

Activity/Output Goal (09PPRDRAOG2.4.5): perform epidemiological and laboratory studies to elucidate mechanisms of beryllium-induced disease, including studies that clarify the role of genetic susceptibility in developing immunological sensitization to beryllium and chronic beryllium disease; and the role of gene-environment interactions.

Strategic Goal 3 (09PPRDRSG3):
Prevent and reduce work-related respiratory infectious diseases.
It should be noted that surveillance is critical to the IG and OG supporting the respiratory infectious diseases strategic goal. Surveillance is needed to document baseline conditions and the impact of intervention and prevention efforts. Education, communication, information
dissemination, and providing support to standard-setting and regulatory groups are also critical to achieving intermediate outcomes that demonstrate impact.

Intermediate Goal (09PPRDRIG3.1): Develop improved approaches to detect and quantify exposures to airborne infectious agents and settled infectious agents with the potential to cause respiratory infection.

Activity/Output Goal (09PPRDRAOG3.1.1): develop database of methods for anthrax exposure assessment.

Activity/Output Goal (09PPRDRAOG3.1.2): develop and validate novel sampling and analytical methods for assessing exposures to airborne infectious agents such as influenza virus.

Activity/Output Goal (09PPRDRAOG3.1.3): develop, improve and validate direct-reading methods for assessing exposures to airborne and settled infectious agents with the potential to cause respiratory infection.

Intermediate Goal (09PPRDRIG3.2): Elucidate pathogen and host factors underlying susceptibility to transmission of occupational respiratory infectious diseases.

Activity/Output Goal (09PPRDRAOG3.2.1): evaluate the impact of occupational exposures on susceptibility to respiratory infection, including underlying mechanisms. Occupational exposures of current concern include welding fume and its constituents; diesel exhaust; residual oil fly ash (ROFA); silica; and potentially others, if evidence suggests that exposure increases risk of respiratory infection.

Activity/Output Goal (09PPRDRAOG3.2.2): evaluate the impact of pathogen characteristics on airborne disease transmission, including aerosol size distribution; impact of factors such as temperature, humidity and UV irradiation on aerodynamic properties, viability and infectivity; and pathogen/environmental factors that affect re-aerosolization of settled agents. Use these findings to develop approaches for predicting the relative importance of airborne and contact disease transmission.

Activity/Output Goal (09PPRDRAOG3.2.3): Apply available basic and epidemiologic data to developing approaches to risk assessment for airborne transmission of occupational infectious agents.

Intermediate Goal (09PPRDRIG3.3): Reduce exposure to airborne occupational infectious agents through engineering controls.

Activity/Output Goal (09PPRDRAOG3.3.1): Develop and disseminate information to improve engineering controls applicable to TB and other agents, including ventilation and modeling of air flow, air filtration, and disinfection via UV germicidal irradiation.

Activity/Output Goal (09PPRDRAOG3.3.2): Develop, demonstrate, and disseminate methods for "expedient airborne isolation" that can be deployed in settings such as epidemics where there is high demand for airborne isolation rooms.

Intermediate Goal (09PPRDRIG3.4): Reduce exposure to airborne occupational infectious agents through respiratory protection.

Activity/Output Goal (09PPRDRAOG3.4.1); develop respirators with better sealing characteristics through improved anthropomorphic facial panels; develop a total inward leakage standard that would provide consumers with an assessment of the fitting characteristics of respirators; and perform research to assess the optimal methods and frequency of fit-testing.

Activity/Output Goal (09PPRDRAOG3.4.2): perform research to assess the possibility of decontamination and re-use of disposable N95 filtering face piece respirators under conditions of respirator shortage.

Activity/Output Goal (09PPRDRAOG3.4.3): complete the development of Chemical, Biological, Radiological, and Nuclear respirator certification standards

Activity/Output Goal (09PPRDRAOG3.4.4): develop and disseminate information products to improve the use of respirators

Intermediate Goal (09PPRDRIG3.5): Reduce the burden of airborne occupational respiratory infectious disease through improved medical screening methods.

Activity/Output Goal (09PPRDRAOG3.5.1): develop and evaluate new methods in medical screening and surveillance for TB infection as an alternative to tuberculin skin testing.

Activity/Output Goal (09PPRDRAOG3.5.2): develop improved strategies for early identification and isolation of infectious cases.

Intermediate Goal (09PPRDRIG3.6): Reduce the burden of airborne occupational respiratory infectious disease through coordination and collaboration with other elements of CDC.

Activity/Output Goal (09PPRDRAOG3.6.1): continue to work with other elements of CDC in the implementation of the Federal Interagency TB Prevention Plan.

Activity/Output Goal (09PPRDRAOG3.6.2): continue to work with other elements of CDC in the development and implementation of a pandemic influenza prevention plan including outreach to multiple industries.

Activity/Output Goal (09PPRDRAOG3.6.3): continue to work with other elements of CDC in the development and implementation of a cross-CDC environmental microbiology research program.

Strategic Goal 4 (09PPRDRSG4):
Prevent and reduce work-related respiratory malignancies.
The lead program for work-related cancer research, including research related to work-related respiratory cancers, is the NIOSH Cancer, Reproductive, and Cardiovascular Diseases (CRC) program. As noted in the NA report on NIOSH respiratory diseases research, respiratory cancers are best approached within the context of a comprehensive cancer program. This is because a single type of carcinogenic exposure may cause many types of cancer. Also, many research and prevention approaches and issues are common to many types of cancer. The goals specified in this section are those of special interest to the RDRP. Investigators should be sure to also refer to the cancer goals within the NIOSH CRC program. It should be noted that surveillance is critical to the IG and OG supporting the work-related respiratory malignancies strategic goal. Surveillance is needed to document baseline conditions and the impact of intervention and prevention efforts. Education, communication, information dissemination, and providing support to standard-setting and regulatory groups are also critical to achieving intermediate outcomes that demonstrate impact.

Intermediate Goal (09PPRDRIG4.1): reduce the incidence of work-related cancer through research, promotion of carcinogen-free workplaces, and international collaborations.

Activity/Output Goal (09PPRDRAOG4.1.1): develop a national research plan for fiber-induced lung cancer by completing, disseminating and implementing priorities described in the document, "Asbestos and Other Mineral Fibers: A Roadmap for Scientific Research."

Activity/Output Goal (09PPRDRAOG4.1.2): complete a reanalysis of respiratory malignancies in a cohort of chrysotile asbestos textile workers, previously studied only by light microscopy, whose exposures will be reanalyzed by EM. This will allow modeling of exposure- response that takes into account the vast majority of fibers that cannot be seen by the light microscopy-based methods previously used to study the cohort.

Activity/Output Goal (09PPRDRAOG4.1.3): conduct epidemiological investigations to better characterize the relationships between exposures to asbestos and other elongated mineral particles, including elongated cleavage fragments of amphibole minerals, and health effects such as interstitial lung disease, lung cancer, and mesothelioma (same as 09PPRDROG2.3.4).

Activity/Output Goal (09PPRDRAOG4.1.4): Elucidate mechanisms of silica-induced lung cancer and reduce silica exposures (exposure reduction is discussed in the interstitial lung diseases section).

Activity/Output Goal (09PPRDRAOG4.1.5): Evaluate a cohort of workers at three beryllium processing facilities to assess the association between lung cancer mortality and quantitative metrics of cumulative, average and peak exposures.

Activity/Output Goal (09PPRDRAOG4.1.6): continue to follow the Colorado Plateau uranium miners' cohort to assess lung cancer risk associated with radon exposure 20 to 40 years after exposure, as well as interactions between radon exposure and smoking.

Activity/Output Goal; Goal (09PPRDRAOG4.1.7): prevent and reduce respiratory diseases associated with exposure to diesel particulate matter (DPM), including lung cancer by: a) improving technologies for DPM assessment and control in underground mining; b) providing technical guidance, through workshops and intervention studies, for the use of control technologies and monitoring to reduce DPM exposure in miners; c) evaluating the relationship between a miner's exposure to DPM and mortality, including lung cancer mortality, in a large cohort study.

Activity/Output Goal; Goal (09PPRDRAOG4.1.8): Evaluate the ability of single-walled and multi-walled carbon nanotubes to cause chromosomal abnormalities in target cell populations *in vitro* and *in vivo*.

Intermediate Goal (09PPRDRIG4.2): reduce mortality from work-related cancer by developing, testing, and implementing methods for early detection of work-related cancer.

Activity/Output Goal (09PPRDRAOG4.2.1): develop and test improved biomarkers for early detection of occupational carcinogenesis. Via a Cooperative Research and Development Agreement, assess the applicability of using alterations in gene expression and gene copy number that have been identified as important in the development of murine lung adenocarcinoma as aids in the early detection and diagnosis of occupationally-induced human lung cancer.

Activity/Output Goal (09PPRDRAOG4.2.2): develop and validate biomarkers of exposure to occupational carcinogens or biomarkers for early detection of occupational respiratory cancer that address the needs of specific occupational groups at high lung cancer risk. Examples include evaluation of *mdig*[17] expression for the early detection of silica-induced lung cancer and
the used of blood biomarkers such as serum osteopontin or soluble mesothelin-related peptide for the early detection of mesothelioma.

Strategic Goal 5 (12PPRDRSG5):
Advance cross-cutting issues that affect all work-related respiratory diseases, in particular surveillance, exposure assessment, and emerging issues

Intermediate Goal (12PPRDRIG5.1): improve surveillance and workforce screening for work-related respiratory diseases.

Activity/Output Goal (12PPRDRAOG5.1.1): develop, demonstrate, and disseminate innovative approaches to surveillance for work-related respiratory diseases, including use of information from the healthcare system such as information in electronic health records (EHR).

Activity/Output Goal (12PPRDRAOG5.1.2): develop and disseminate practical and appropriate standards for coding and entering industry and occupation (I/O) information into ambulatory and inpatient electronic medical records.

Activity/Output Goal (12PPRDRAOG5.1.3): demonstrate utility ("meaningful use") of occupation and industry information in electronic health records with respect to the recognition, diagnosis, and management of a work-related disease such as work-related asthma.

Activity/Output Goal (12PPRDRAOG5.1.4): conduct surveillance for work-related respiratory diseases using available data sources, including mortality data, cancer center data, other national data sources or studies, and/or State-based surveillance, with ongoing analysis and dissemination of results.

Activity/Output Goal (12PPRDRAOG5.1.5): develop and implement innovative approaches to disseminating surveillance data, such as an on-line query system that permits stakeholders and interested parties to obtain comprehensive up-to-date information on the prevalence of work- related respiratory diseases such as CWP.

Activity/Output Goal (12PPRDRAOG5.1.6): transition from film-based chest radiography to modern digital chest imaging in screening programs for occupational and other lung diseases. Pursue a range of relevant efforts including technology validation and improvement; development and dissemination of guidance; and development and dissemination of training and competency testing opportunities.

Activity/Output Goal (12PPRDRAOG5.1.7): improve the practice and science of spirometry in workforce screening programs. Improve training of technicians and develop practical tools to help them perform high quality spirometry. Improve recommendations and practice of using longitudinal spirometry for early recognition of declining lung function.

Intermediate Goal (12PPRDRIG5.2): improve exposure assessment for work-related respiratory diseases: develop, validate and disseminate sampling strategies, sampling and analytical methods, and methods for evaluating results of environmental investigations to better characterize exposures to occupational agents that can cause or exacerbate work-related respiratory diseases.

Activity/Output Goal (12PPRDRAOG5.2.1): develop, validate and disseminate methods for detection and quantitation of semi-volatile organic compounds (e.g., diacetyl and related flavorings).

Activity/Output Goal (12PPRDRAOG5.2.2): develop, validate and disseminate methods for detection and quantitation of nanomaterials (e.g., carbon nanotubes and TiO_2).

Intermediate Goal (12PPRDRIG5.3): address new and emerging issues in work-related respiratory diseases not addressed elsewhere in these strategic goals.

Activity/Output Goal (12PPRDRAOG5.3.1): perform basic *in vitro* and *in vivo* toxicology studies to evaluate for respiratory toxicity of nanoparticles and, if present, to characterize nanoparticle characteristics and mechanisms of action underlying toxic effects.

Activity/Output Goal (12PPRDRAOG5.3.2): develop partnerships and conduct field evaluations of facilities where nanomaterials are produced or used to document exposures and assess for potential adverse health effects.

Activity/Output Goal (12PPRDRAOG5.3.3): develop and disseminate guidance documents on medical surveillance and use of control banding in facilities where nanomaterials are produced or used.

Activity/Output Goal (12PPRDRAOG5.3.4): conduct a range of studies to better understand exposures, toxicities, human health effects, and prevention of alveolar proteinosis, interstitial lung disease, and potentially other effects of workplace exposure to indium tin oxide.

Activity/Output Goal (12PPRDRAOG5.3.5): conduct a range of studies to better understand exposures, toxicities, human health effects, and prevention of respiratory diseases resulting from recent natural and man-made disasters, including the Deep Horizon/Gulf oil spill, pandemic H1N1 influenza, floods such those following Katrina, and the World Trade Center disaster.

Appendix 2

Occupational Respiratory Disease Surveillance

Original peer reviewed reports - Surveillance (2008-2012)

Work-related asthma

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Appendix 3

Digital Chest Imaging

Digital Chest Imaging, Products 2008-2012

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Appendix 4

Flavorings-Related Lung Disease

Flavorings-Related Lung Disease, 2008-2012

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Appendix 5

Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease / Spirometry: 2008-2012

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Appendix 6

Work-Related Asthma

Work-Related Asthma: 2008 – 2012

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